

REMARKS

I. The Rejection Under 35 U.S.C. 112, Second Paragraph, May Be Properly Withdrawn

The Examiner rejects claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully requests reconsideration of this rejection.

Applicant amends the claims as noted in the above section. Support for these amendments to the claims is found throughout the specification, and as such no new matter is presented in the amendments. Applicant respectfully submits that these amendments to the claims obviate the Examiner's rejection under 35 U.S.C. 112, second paragraph, and thus, this rejection may be properly withdrawn. Applicant respectfully requests withdrawal of this rejection.

II. The Rejection Under 35 U.S.C. 102(b) May Be Properly Withdrawn

The Examiner rejects claims 1-2, 4-9, and 11 under 35 U.S.C. 102(b) as being anticipated by the disclosures of Thistlethwaite et al. (U.S. Patent 5,402,240) or Wiesman (U.S. Patent 5,983,661). The Examiner contends that these references teach inseminating animals with a composition that comprises semen, an extender, a prostaglandin and an antibiotic. Applicant respectfully traverses this rejection.

A patent is invalid for anticipation under 35 U.S.C. 102(b) if a single prior art reference discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)) The prior publication must disclose in an enabling manner the invention that is in question. Applicant respectfully submits that these criteria are not met in the Examiner's rejection.

Applicant's invention is a method for reducing the number of insemination administrations to a female mammal in one service period comprising the step of administering to the female native or extended semen with a simultaneous or sequential administration of a prostaglandin. Also, it is a novel composition of matter that includes either native semen, extended semen, or a semen extender, one or more prostaglandins, and optionally, one or more antibiotics.

The Thistlethwaite patent is directed to "an instrument for measuring sperm concentration and calculating dose value and having an optical assembly with a light source, a specimen holder and a photodetector, a computation unit, a display, and a storage unit for storing a concentration calculation equation." (Abstract) The most it says about additions to semen is: "The stored semen should be mixed with a pre-warmed life extending blend of chemicals and antibiotics (extender) in preparation for the insemination procedures..." (Column 1, Lines 57-60) However, nowhere does it define the blend of chemicals or identify the antibiotics. Thus, Thistlethwaite does not claim or enable Applicant's

invention. It does not teach or suggest Applicant's invention because it does not disclose or contemplate a method for reducing the number of insemination administrations to a female mammal in one service period nor does it teach or suggest a novel composition of matter as described above for the instant application.

The Wiesman patent "relates to an inexpensive, self-contained, thermally insulated, disposable, refrigerated transport container arrangement that can greatly extend the length of time over which the spermatozoa of equine semen can be maintained motile and fertile, and thus render it possible to effectively transport this type of material over long distances." (Column 1, Lines 16-22) In several sections of this patent, the composition of the extender is described as containing two sugars (glucose and sucrose), non-fat dry milk solids, at least one antibiotic, cell culture tested water, plus any chemicals (e.g., sodium carbonate or sodium bicarbonate) required to adjust the pH and/or osmolality. (Column 6, Lines 52-67; Column 7, Lines 1-21; Column 10, Lines 25-32; Column 11, Lines 8-12; Column 12, Lines 61-65; Column 18, Lines 37-42; Column 19, Lines 49-55) Wiesman does not contemplate the use of a prostaglandin in the extender or during the insemination process. Thus, the Wiesman patent does not claim or enable Applicant's invention. It does not teach or suggest Applicant's invention because it is directed to extending the viable life of spermatozoa during transportation, particularly by temperature regulation, and not to reducing the number of insemination administrations to a female mammal in one service period. In addition, the composition of the extender described in the Wiesman patent does not include a prostaglandin as does the instant invention.

Because neither the Wiesman patent nor the Thistlethwaite patent teaches each and every limitation of Applicant's invention, Applicant respectfully submits that this rejection under 35 U.S.C. 102(b) may be properly withdrawn.

III. The Rejection Under 35 U.S.C. 103(a) May Be Properly Withdrawn

The Examiner rejects claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Thistlethwaite et al. or Wiesman in view of Bowler et al. (U.S. Patent 4,004,021) and Hayashi et al. (U.S. Patent 3,953,495). The Examiner contends that Thistlethwaite and Wiesman teach inseminating animals with a composition that comprises semen, an extender, a prostaglandin and an antibiotic. The Examiner also contends that the administration of prostaglandins to a female mammal to improve impregnation is notoriously old and well known in the art as taught by Hayashi and Bowler. Applicant respectfully traverses this rejection.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be

considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

As discussed in Paragraph 2 above, neither Thistlethwaite nor Wiesman disclose or contemplate the instant invention. They do not teach or enable a method for reducing the number of insemination administrations to a female mammal in one service period comprising the step of administering to the female native or extended semen with a simultaneous or sequential administration of a prostaglandin. In addition, the composition of the extender is not described in the Thistlethwaite patent, and the extender described in the Wiesman patent does not include a prostaglandin, as does the present invention.

The Hayashi patent relates to 16-methylene prostaglandins. (Abstract) It states that the new prostaglandin compounds are useful in the control of estrus in female mammals... for example, in order to facilitate artificial insemination... (Column 12, Lines 65-68) However, the control of estrus relates to controlling the timing of the estrus period (e.g., "short-cycling" the period) and the timing of when the subjects should be inseminated and not the number of times the inseminations need be performed. For the control of estrus, the prostaglandin would be administered via injection (intramuscular, subcutaneous, or intravenous) and would not be added to the native or extended semen sample.

The Hayashi patent also states that the new prostaglandin compounds possess "luteolytic activity, stimulatory activity on uterine contraction and antiniditory activity in female mammals." (Column 12, Lines 60-62) These activities are consistent with the compounds' actions "in the induction of labor in pregnant female mammals,... in the procurement of abortion in pregnant female mammals, in the prevention of pregnancy in female mammals,..." (Column 13, Lines 1-5) (See also Column 13, Lines 15-22; Lines 29-31, Lines 66-68; Column 14, Lines 1-9; Column 21, Lines 50-57) As stated above, the use of the compounds of the Hayashi patent for artificial insemination is through the compounds' ability to control the female estrus cycle not through the addition to semen. There is no suggestion or motivation to combine the teachings of Hayashi with those of Thistlethwaite or Wiesman to add the compounds to semen. Indeed, there is no reason to expect that adding the abortifacients of Hayashi's teachings to native or extended semen would result in success at reducing the number of insemination administrations to a female mammal.

The Bowler patent relates to novel pentanor prostaglandin analogues, a process for their manufacture, compositions containing them, and their use in a method of inducing luteolysis. (Abstract) Among the uses ascribed to these compounds is that they "are useful for addition to semen intended for artificial insemination of domestic animals, the success rate of insemination being thereby increased, especially in pigs and cattle." (Column 1, Lines 30-33) The success rate of insemination is generally measured by whether or not pregnancy is established. This is different than the focus of the present invention, which relates to a reduction in the number of inseminations in one service period. Through the method of the present invention, the number of times a subject may need to be inseminated in one service period may be reduced from up to 5 administrations by at least 20% to up to 80 percent. After the insemination administration the subject may no longer be in heat and thus not require additional inseminations during that service period. The insemination may or may not result in pregnancy, but that cannot be determined for a length of time following insemination, with the length depending on the species involved. For example, sows are usually monitored by ultrasound approximately 30 days following insemination administration to determine whether or not pregnancy was established.

Applicant respectfully submits that none of the references cited by the Examiner suggest Applicant's invention. There is no indication in any of the references that would suggest that the references be combined. Moreover, even when combined the references do not yield Applicant's invention. Because none of the references, alone or in combination, teaches Applicant's invention, Applicant respectfully submits that this rejection under 35 U.S.C. 103(a) may be properly withdrawn.

Conclusion

In view of the amendments and remarks made herein, Applicant respectfully submits that claims 12-32 are in condition for allowance and respectfully requests expedited notification of same.

Respectfully submitted,



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